Technical Instructions to Panel Physicians for Vaccination Requirements

I. Introduction

On September 30, 1996, the U.S. Congress amended the Immigration and Nationality Act (INA) by adding to the health-related grounds of inadmissibility a new subsection, "Proof Of Vaccination Requirements For Immigrants". This new subsection requires any person who seeks an immigrant visa to show proof of having received vaccination against vaccine-preventable diseases as recommended by the U.S. Advisory Committee on Immunization Practices (ACIP). The ACIP is an advisory committee to the Centers for Disease Control and Prevention (CDC) that makes general recommendations on immunizations, including safe and effective vaccination schedules. Updated ACIP recommendations are available at CDC's National Immunization Program (NIP) website: http://www.cdc.gov/nip/publications/ACIP-list.htm.

The U.S. Immigration and Naturalization Services (INS) has determined that the vaccination requirements do not apply to refugees and nonimmigrants, such as V or K visa applicants, at the time of their initial admission to the United States. However, refugees and V and K visa holders must meet the vaccination requirements when applying for adjustment of status or permanent resident status in the United States (one year or more after arrival). Therefore, for refugee applicants, panel physicians must complete a U.S. Department of State Vaccination Documentation Worksheet (DS-3025) if reliable documents are available.

Significant changes in the *Technical Instructions* for immunization requirements

- Hepatitis B vaccine required through 19 years of age.
- Influenza vaccine required for those 50 years of age or older.
- Pneumococcal conjugate vaccine required for children younger than 24 months of age.
- Inactivated polio vaccine (IPV) generally preferred over oral polio vaccine (OPV).
- Additional information on distinguishing contraindications from other conditions when vaccines may be given.
- Emphasis on physician's medical judgement in consideration of existing precautions.
- Emphasis on the physician's educating applicants on the importance of completing vaccine series and providing a record of "Vaccines To Complete" (Appendices B and C)
- Resources for additional publications and materials to assist the physician.
- Emphasis on properly maintaining vaccines and following precautions in administering vaccines (Appendix E).

CDC's Division of Global Migration and Quarantine (DQ) staff are available for consultation on issues relating to interpretation of the *Technical Instructions to Panel Physicians for Vaccination*

Requirements and can be reached by fax at 001-404-498-1633. These Technical Instructions and updates on immunization requirements are available via the Internet on DQ's site online at: http://www.cdc.gov/ncidod/dq/technica.htm.

II. ROLE OF THE PANEL PHYSICIAN

The panel physician is responsible for following CDC procedures and guidelines in providing services.

Vaccination Requirements for Immigrant Visa Applicants

All immigrant applicants must be assessed for vaccination requirements. The panel physician must review all vaccination records presented by the applicant during this process and record the vaccination assessment results on a DS-3025. Those vaccines determined to be required must be administered. The panel physician may refer the applicant to another health care provider to receive required vaccinations. In such a case, the panel physician must not complete the form until the applicant returns with a written record from the referral health care provider that notes the vaccines administered and the dates of administration.

Before administering any vaccines, the panel physician must screen the applicant for contraindications and precautions and discuss with the applicant any adverse reactions. After administering any needed vaccines, the panel physician must complete a DS-3025 and provide a copy of the completed form to the applicant for his or her personal records.

At this point, the applicant will have fulfilled the vaccination requirements; however, if any vaccine series is not complete, it is imperative that the panel physician stress the need for the applicant to complete the series. A copy of "Vaccines to Complete" (Appendices B and C) must be provided to the applicant and updated each time a vaccine is administered to the applicant.

III. VACCINATION HISTORY

Review of Vaccination Records

The panel physician should encourage the applicant to submit all available written records of vaccination history for review. These records can include records from the applicant's country of origin and, for refugees, records of vaccination from refugee camps or countries of asylum. Although refugees are not required to receive vaccines overseas, panel physicians must complete Part I of the DS-3025 if reliable documents are available (see DQ's site online at: http://www.cdc.gov/ncidod/dq/dsforms for additional instructions).

Vaccinations Received Outside the United States

The majority of vaccines used worldwide are from reliable local or international manufacturers; it is reasonable, therefore, to assume that any vaccine received by an applicant was of adequate potency. However, the vaccination schedules should be consistent with those recommended in the United States. If there are questions, DQ, CDC may be contacted by telephone at 001-404-498-1600 or by fax at 001-404-498-1633.

Vaccination Documentation

Acceptable vaccination documentation must come from a vaccination record, either a personal vaccination record or copy of a medical chart record with entries made by a physician or other appropriate medical personnel. Self-reported doses of vaccines without written documentation are not acceptable. Only those records of doses of vaccines that include the dates of receipt (month, day, and year) are acceptable. The document must not appear to have been altered, and dates of vaccinations should seem reasonable and not made up. The panel physician's judgement in assessing the validity of the records is expected and acceptable.

Review History of Acute, Vaccine-Preventable Diseases

The panel physician should obtain a good history of acute, vaccine-preventable diseases, including measles, mumps, rubella, and varicella, from the applicant to identify any naturally acquired diseases for optional laboratory confirmation (see section IV, "Laboratory Support"). An applicant who provides a reliable written or oral history of varicella disease does not require laboratory confirmation or further vaccination.

Identify Any Past or Present Condition That Might Be a Contraindication to Vaccination

General Contraindications for the Administration of a Vaccine

- A history of anaphylactic or anaphylactic-like reactions for a specific vaccine or a vaccine constituent.
- Presence of a moderate or severe illness with or without a fever.
- Severely immunocompromised conditions for receiving live attenuated vaccines: measles-mumps-rubella (MMR) vaccine, oral poliovirus vaccine (OPV), and varicella vaccine.
- Pregnancy for receiving live attenuated vaccines (MMR, OPV, and varicella), and inactivated poliovirus vaccine (IPV).
 - MMR: MMR and its component vaccines should not be administered to women known to be pregnant. Nonpregnant women should avoid becoming pregnant for one month after receiving MMR or other rubella-containing vaccines.
 - Polio: Although no adverse effects of IPV or OPV have been documented in pregnant women or their fetuses, vaccination should be avoided on theoretical grounds.
 - Varicella: The effects of varicella vaccine on the fetus are unknown. Pregnant women should not be vaccinated, and nonpregnant women should avoid becoming pregnant for one month after receiving varicella vaccine.

Major contraindications to specific vaccines are shown in Table 3. For pregnant women, contraindications and precautions are shown in Table 4.

Not Contraindications for the Administration of a Vaccine

- Mild to moderate local reactions to a previous dose of vaccine.
- Mild acute illness with or without low-grade fever.
- Recovering from an illness.
- Pregnancy for tetanus and diphtheria toxoids (Td) vaccine, tetanus toxoid (TT) vaccine, or hepatitis B (HepB) vaccine.
 - Td/TT: There is no known risk of adverse effects to developing fetuses when Td/TT is administered to pregnant women.
 - HepB: There is no known risk of adverse effects to developing fetuses when HepB is administered to pregnant women.
- Breast-feeding.
- Diarrhea.
- Current antimicrobial therapy.

Certain conditions are considered precautions rather than true contraindications for vaccination. The difference between a contraindication and a precaution is explained in Appendix D (page D-5).

Precautions for the Administration of a Vaccine

- Fever of 40.5° Celsius (C) (105° Fahrenheit [F]) or more within 48 hours after vaccination with a prior dose of diphtheria and tetanus toxoids and pertussis vaccine (DTP) or diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). Because such febrile reactions are usually attributed to the pertussis component, vaccination with DT should not be discontinued.
- Seizures within 3 days of receiving a prior dose of DTP or DTaP.
- Persistent, inconsolable crying lasting 3 hours or longer within 48 hours of receiving a prior dose of DTP or DTaP.

There can be circumstances, such as a high incidence of disease or disease-related morbidity or mortality, in which the potential benefits outweigh possible risks of vaccination, particularly if these events are not associated with permanent sequelae. The panel physician should weigh these risks and benefits and determine vaccine eligibility. If the decision to defer a vaccine is reached, this decision should be recorded as a medical contraindication.

IV. LABORATORY SUPPORT

Evidence of Immunity

Laboratory evidence of immunity is acceptable for the following diseases: measles, rubella, mumps,

hepatitis B, polio, and varicella (normally not necessary unless a history of varicella disease is questionable).

Serologic Tests

Acceptable tests for the presence of antibodies consist of U.S. Food and Drug Administration (FDA)-approved kits, Clinical Laboratory Improvement Amendments (CLIA)-certified kits, or kits approved by similar agencies outside the United States. In the use of any approved kits, the manufacturer's guidelines or instructions must be followed, including not using a kit which is past its expiration date or which has not been maintained according to manufacturer's directions (for example, not refrigerated as required). Standard precautions in drawing blood (for example, disposable gloves or sterile needles) and appropriate needle disposal must also be followed (see section VII).

V. DIAGNOSIS AND CLASSIFICATION: PROCEDURE FOR VACCINATION ASSESSMENT STATUS AND COMPLETION OF THE VACCINATION DOCUMENTATION WORKSHEET (FORM DS-3025)

Tools To Perform Vaccination Assessment

The following instructions and accompanying tables are based on recommendations by the ACIP. ACIP recommendations are directed to health care providers who are generally in primary care medicine and provide vaccinations. However, because circumstances and disease prevalence often differ in other countries, and because panel physicians normally see applicants only one time, the ACIP's recommendations are not completely applicable to practices that occur in foreign countries. As a result, these instructions and tables have been developed to provide guidance to panel physicians performing the medical examinations and vaccination assessments.

The tables and forms in the following lists are to be used in conjunction with the written instructions.

Table 1	Required Vaccines for Immigrant Visa Applicants With Incomplete Records
by Age Group.	
Table 2	Vaccine Schedule for Routine Immunizations.
Table 3	Major Contraindications to Vaccinations Listed in Tables 1 and 2.
Table 4	Vaccines for Pregnant Women.
Appendix A	U.S. Department of State Vaccination Documentation Worksheet (DS-3025)
Appendix B	Vaccines To Complete for Children and Adolescents.
Appendix C	Vaccines To Complete for Adults.

Procedure for Determining Vaccine Status for Each Vaccine

The panel physician is responsible for:

- Determining the age of each applicant.
- Reviewing each applicant's medical history and records.
- Determining the vaccines each applicant needs.
- Assessing contraindications.
- Assessing each applicant's laboratory needs.

Assessing laboratory needs includes:

- Scheduling a follow-up visit to complete assessment for a vaccine if the applicant chooses to have laboratory tests for immunity.
- Reviewing the applicant's laboratory results for immunity.

After following the preceding procedures, the panel physician can determine the initial vaccine status of an applicant. If the panel physician determines that the vaccination status of the applicant is incomplete, the panel physician is responsible for:

- Determining that vaccines to be given are potent.
- Administering a vaccine dose to the applicant if results do not indicate immunity.
- Scheduling a follow-up visit to complete the assessment for a vaccine if the applicant is referred to another health care provider for the required vaccine dose.
- Reviewing the documentation of the vaccine dose administered by the other provider as soon as it is provided by the applicant.

Procedure for Completing the Vaccination Documentation Worksheet (Form DS-3025)

The panel physician is responsible for:

- Completing the applicant identification information.
- Copying the dates of all acceptable documented vaccinations from written records under "Part 1. Immunization Record" in the appropriate "Date Received" of DS-3025. Any vaccine administered by the panel physician is to be indicated in the "Vaccine Given by Panel Physician" section of DS-3025.
 - Doses should be recorded chronologically (month, day, and year as numbers corresponding to mm, dd, and yyyy), from left to right.

- Completing the vaccination series.
 - If the applicant has completed the vaccination series, the "Completed Series" box for each vaccine must be checked on DS-3025. If a vaccine is given during the assessment resulting in the applicant's becoming fully immune, the "Completed Series" box for that vaccine must be checked.
 - If, as a result of a laboratory test, the applicant is identified as fully immune, the month, day, and year of the test must be written in the "Completed Series" box for each applicable vaccine.
 - If a reliable written or oral history of varicella disease is given, "VH" (varicella history) must be written in the "Completed Series" box for varicella.
- Reviewing any incomplete vaccination series not medically appropriate.

In many cases, it might not be medically appropriate to administer a dose of a particular vaccine. There are five "Not Medically Appropriate" categories that are acceptable when determining an applicant's eligibility for a blanket waiver. A blanket waiver is a waiver that is applied uniformly to a group of conditions and does not require a separate waiver application or fee to be filed with INS. The five "Not Medically Appropriate" categories are:

• Not appropriate age

Table 1 shows which vaccines are indicated based on the age of the applicant at the time of the medical examination. For each vaccine for which administration is not age appropriate, the "Not age appropriate" waiver box must be checked. This will occur for some vaccines for each applicant, such as an infant not needing the influenza vaccine or an adult not needing the *Haemophilus influenza* type b vaccine.

Insufficient time interval between doses

Table 2 is the recommended routine schedule for vaccines administered in the United States. If the minimum time interval between the last documented dose and the next required dose has not passed, the "Insufficient time interval" waiver box for that vaccine must be checked.

If administration of the single dose of a vaccine at the time of the medical examination does not complete the series for that vaccine, the "Insufficient time interval" waiver box must be checked to indicate that additional doses would be required to complete the series for that vaccine.

Contraindication

The major contraindications are shown in Table 3, and the general contraindications to specific vaccines are shown under section III, "Vaccination History". If an applicant has a contraindication, the "Contraindication" waiver box for that vaccine must be checked.

• Vaccine unavailable in country where medical examination is performed

When the required vaccine is not licensed or not routinely available in the country where the medical examination is performed, the "Not routinely available" waiver box must be checked.

• Outside seasonal administration of influenza vaccine

As indicated in Table 2, influenza vaccine is required during the influenza (flu) season. The flu season begins during the fall season for the northern hemisphere, but can be other times of the year elsewhere. However, the influenza vaccine might only be available during fall. Therefore, the "Not fall (flu) season" waiver box must be checked at other times of the year.

- Completing "Part 2. Results".

 After reviewing entries in "Part 1. Immunization Record" for all the vaccines, only one appropriate box under "Part 2. Results" must be checked.
 - Vaccination history incomplete—Applicant may be eligible for blanket waivers(s).

Completion of a vaccine series is not required to conclude the medical examination because such a requirement would require multiple visits to a panel physician and could lead to unnecessary delay in the immigration process. If any of the boxes under the "Not Medically Appropriate" heading was checked, the "Applicant may be eligible for blanket waiver(s) because vaccination(s) not medically appropriate (as indicated above)" box must be checked. This will probably always be checked because some vaccines may not be age appropriate for the applicant, unless he or she requests a waiver based on religious or moral convictions or refuses vaccination.

• Vaccine history incomplete—Applicant will request a waiver based on religious or moral convictions.

If an applicant objects to vaccination based on religious or moral convictions, the appropriate "Applicant will request an individual waiver based on religious or moral convictions" box must be checked. This is not a blanket waiver, and the applicant will have to submit a waiver request to the INS.

• Vaccine history complete for each vaccine.

If the applicant has met vaccination requirements for each vaccine recommended, the "Vaccine history complete for each vaccine, all requirements met" box must be checked; however, this will probably not occur.

• Applicant does not meet immunization requirements.

If an applicant's vaccine history is incomplete and the applicant refuses administration of a single dose of any recommended vaccine that is medically appropriate for the applicant, the "Applicant does not meet immunization requirements" box must be checked.

• Completing "Part 3. Panel Physician".

The panel physician should review the entire DS-3025 for completeness and accuracy before signing the document. It is important that the document be legible, and all names and dates be either printed or typed. The primary intent of this document is for presentation to the INS to meet immigration vaccination requirements. However, an extra copy must be provided to the applicant; it is an important vaccination record that might be used later by other health care providers, and schools and other institutions. The panel physician's signature on this document signifies the reliability of the document to the best of the physician's knowledge. The signature should be an original or a stamp of the panel physician's signature.

• Completing "Vaccines To Complete for Children and Adolescents (or Adults)".

The panel physician must also fill out the "Vaccines to Complete" form (Appendix B or C) and provide it to the applicant as a record showing vaccines that need to be further administered to complete the series of vaccination. This form is self-explanatory.

VI. INFECTION CONTROL AND SAFETY ISSUES

Appendix E, "Vaccination Handling and Administration for Panel Physicians", provides information on appropriate equipment and standard operating procedures to ensure the potency of vaccines. If

vaccines are not properly handled or stored, their potency is reduced, and they may not produce immunity. Therefore, proper handling and storage are important.

Additional guidance can be found in the CDC publication, "Vaccine Management, Recommendations for Handling and Storage of Selected Biologicals", which can be obtained from NIP. This publication can be found in *Epidemiology and Prevention of Vaccine-Preventable Diseases* or at www.cdc.gov/nip and under "NIP publications", selecting "Vaccine Management, Recommendations for Handling and Storage of Selected Biologicals". Additional guidance is available in the CDC publication "Guidelines for Vaccine Packing and Shipping". Both publications can also be obtained by contacting the Immunization Services Division, NIP at 001-404-639-8823 or by fax at 001-404-639-8720.

Precautions in Administering Vaccines

People administering vaccines should take the following necessary precautions to minimize the risk of spreading disease.

- They must wash their hands before and after seeing each applicant.
- They must wear gloves when administering vaccinations if they will have contact with potentially infectious body fluids or have open lesions on their hands.
- They must use sterile syringes and needles and preferably use disposable, autodestructible ones to minimize risk of contamination or needle stick.
- They must not mix different vaccines in the same syringe unless the vaccines are licensed for such use.
- They must discard disposable needles (not recap them) and syringes in labeled, puncture-proof containers for short-term disposal to prevent inadvertent needle stick injury or reuse.
- They must use an appropriate method, such as autoclaving or incineration, for long-term disposal of used needles and syringes.

VII. COUNSELING AND RESOURCES

The panel physician must counsel all applicants who do not have a complete series for a vaccine to seek a private physician before or after resettlement in the United States who can assist the applicant in becoming fully vaccinated.

Appendix D, "Questions and Answers on General Administration of Vaccines, General Contraindications and Precautions, and Specific Vaccines for Panel Physicians", provides guidance on required vaccines.

Advisory Committee on Immunization Practices (ACIP) Statements

ACIP statements are published in the *Morbidity and Mortality Weekly Report* (MMWR) periodically. Copies of specific articles can be obtained by:

- Calling CDC's immunization hotline at 800-232-2522.
- E-mailing a request to <nipinfo@cdc.gov>
- Using the National Immunization Program (NIP) website at http://www.cdc.gov/nip and selecting "ACIP Recommendations".

Epidemiology and Prevention of Vaccine-Preventable Diseases

The book *Epidemiology and Prevention of Vaccine-Preventable Diseases* provides an overview of vaccine-preventable infectious diseases and the corresponding vaccines. It serves as a useful companion to the ACIP statements. The appendices provide considerable information and are an invaluable aid for identifying search tools and other resources. This book and other immunization materials are available by:

- Contacting NIP at:
 National Immunization Program
 Information and Distribution Program
 Centers for Disease Control and Prevention
 1600 Clifton Road NE, MS E-34
 Atlanta, GA 30333
 U.S.A.
 800-232-2522
 FAX 404-639-8828
- Using the NIP website at http://cdc.gov/nip, and under "NIP publications", selecting "Epidemiology and Prevention of Vaccine Preventable Diseases".